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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,366	08/06/2003	Jeffrey M. Vitullo	3600/268	1298

1912 7590 11/27/2007  
AMSTER, ROTHSTEIN & EBENSTEIN LLP  
90 PARK AVENUE  
NEW YORK, NY 10016

EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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11/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/635,366

Applicant(s)

VITULLO ET AL.

Examiner

Matthew F. DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, 9-15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Raulerson et al. (USPN 6,551,281).

Raulerson et al. discloses a catheter (10) having a stiffening section 51 as claimed, which is located in the middle of the catheter (see figure 2). The other catheter embodiments shown in figures 5 also show a separation of the catheter-stiffening element from the distal and proximal terminus and a needle hub (28) with a needle (36) see figure 5 and 6 and entire reference.

3. Claims 1-7, 9-15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Orr et al. (USPN 5,263,938).

Orr et al. discloses a catheter (16) with a proximal section (10), a body (24) and a distal section (22) having a stiffening section 68 as claimed, which is located in the middle of the catheter (see figure 10). Orr et al. also shows a needle hub (56) with a needle (54) [see figure 8].

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8, 16, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raulerson et al. or Orr et al. as applied to the claims above.

Raulerson et al. or Orr et al. discloses the invention substantially as claimed except for the stiffening coating having a thickness not exceeding about 0.08mm, and the sleeve being made out of PET. The instant disclosure describes this dimension as being merely preferable, and does not describe it as contributing any unexpected result to the catheter. As such this parameter is deemed matters of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. With respect to the PET material, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Raulerson et al. or Orr et al. with a PET material, since the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325, U.S. 327, 65 USPQ 297 (1945).

***Response to Arguments***

6. Applicant's arguments, filed 9/12/07, with respect to the 102 and 103 Rejections have been fully considered and are not persuasive.

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7. Applicant is arguing that the prior art doesn't teach the claimed invention since the prior art fails to give the same structure the same name. The examiner disagrees with the applicant because the examiner and one of ordinary skill in the art would interpret the structure of the prior art to anticipate the claimed elements. The examiner interprets the claim limitations with the broadest reasonable interpretation, therefore as long as the prior art meets the dictionary definition of the claimed element and is capable of working in the same fashion as the claimed element, then the prior art would anticipate applicant's invention. Therefore the examiner disagrees with applicant's interpretation of the prior art since the prior art reads on the broadest reasonable interpretation of the claimed invention and fails to view the prior art as interpreted by the examiner.

8. With regards to the claimed catheter, the interpretation is a tube like structure that has a lumen, which is shown in both prior art references. The "catheter" of both prior art references are flexible since they are capable of flexing and are made from a polymer and not steel or a metal that is inherently rigid. With regards to function, the examiner interprets this language in view of MPEP section 2114.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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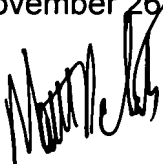
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance call 800-786-9199 (IN USA) or 571-272-1000.

Matthew DeSanto  
Art Unit 3763  
November 26, 2007



MATTHEW F. DESANTO  
PRIMARY EXAMINER